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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/612,770

07/01/2003

James E. Brewer

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4998

36802 7590 11/05/2007  
PACESETTER, INC.  
15900 VALLEY VIEW COURT  
SYLMAR, CA 91392-9221

EXAMINER

GEDEON, BRIAN T

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

11/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

CT

<b>Office Action Summary</b>	<b>Application No.</b> 10/612,770	<b>Applicant(s)</b> BREWER ET AL.	
	<b>Examiner</b> Brian T. Gedeon	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. This action is in response the amendment after-final filed 22 October 2007.

### ***Response to Arguments***

2. Applicant's arguments, see Remarks, filed 22 October 2007, with respect to the rejection(s) of claim(s) 1, 2, 4, 6, 7, 15-19 and 22 under 35 U.S.C. 102(e) as being anticipated by Hill et al. (US Patent no. 6,445,952) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 U.S.C. 102(b) as being anticipated by Hill et al. (US Patent no. 6,195,584).

### ***Oath/Declaration***

3. The Applicant's arguments pertaining to the objection to the oath have been noted and considered. However, the objection pertaining to the oath is maintained, due to a directive issued by the Office pertaining to the disputed language. Applicant is advised that a forthcoming OG Notice will address the duty to disclose language required and set forth means to address any language which varies from that required in both pending and patented applications.

### ***Claim Rejections - 35 USC § 102***

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, 6, 7, 15-19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al. (US Patent no. 6,195,584).

In regard to claims 1, 2, 4, 6, 7, 15-19, and 22, Hill et al. teach that one approach for detecting dislodgement of a medical leads by delivering a test pace pulse the atrium, then immediately sensing the resulting ventricular depolarization from a ventricular sense electrode. The interval of time between the delivered pulse to the sensed depolarization is used to determine if the atrial electrode is properly located in the atrium, col 2 lines 10-24. The device of Hill et al. uses an implantable pulse generator 10 that includes a canister housing that can also serve as an electrode, col 5 lines 32-34. A right ventricle lead 16 contains ventricular pace/sense electrodes, 24, 26, and 28, wherein electrode 24 is a ring electrode, col 4 lines 37-56. A right atrium-superior vena cava lead 15 contains atrial pace/sense electrodes 17, 19, and 21, wherein electrode 21 is a ring electrode, col 4 line 57 – col 5 line 12. There is also a coronary sinus lead 6, col 5 lines 13-21. The electrodes of the device can be used in a unipolar or a bipolar configuration, col 8 lines 46-49.

***Claim Rejections - 35 USC § 103***

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 5, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US Patent no. 6,195,584).

In regard to claims 3, 5, 20, and 21, Hill et al. substantially describes the invention as claimed, except does not claim that the first or second chambers may be one of a right ventricle, left ventricle, or in a vessel. Hill et al. can be used in dual chamber device, col 2 lines 46-57. The device of Hill et al. also contains leads for the right atrium 15, right ventricle 16, and the coronary sinus 6. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus and method of Hill et al. by placing leads in other locations of the heart since Hill et al. since it is well known in the art and not beyond one of ordinary to be able to place leads in any of the cardiac chambers or vessels.

8. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US Patent no. 6,195,584) in view of Digby (US Patent no. 4,173,230).

In regard to claims 8 and 9, Hill et al. substantially describe the invention as claimed except do not teach sensing or pacing during the refractory period. Digby teaches that sensing and pacing can occur during a refractory period, col 4 lines 1-10. Therefore it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to sense and pace during the refractory period in order to artificially extend it.

9. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US Patent no. 6,195,584) in view of Burnes et al. (US Publication no. 2003/0204212).

In regard to claims 10-12, Hill et al. substantially describe the invention as claimed except for measuring parameters relating to the dimensions of the heart. As set forth in Burnes et al. impedance is measured between two sensing locations, which in view of a multi-chamber pacing system implies that impedance can be measured between two different chambers of the heart. The impedance measurements are associated with cardiac geometry since Burnes et al. teach that maximum impedance is indicative of minimum cardiac volume, para 0018. Further, impedance measurements are taken across the heart at certain cardiac cycle times as a measure of chamber expansion or contraction, which the Examiner considers to be parameters related to cardiac geometry, para 0012. In view of the fact that impedance is the ratio between voltage potential and current and of the teachings regarding impedance sensing of Burnes et al., the Examiner takes the position that potential is necessary if not inherently being measured. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hill et al. with the methods for dimension measurements of Burnes et al. since both references teach methods for sensing potentials across the heart in order to ascertain parameters relating to

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dimensions (i.e., Hill et al. determine as distance between electrodes, and Burnes et al. determine cardiac geometry.

In regard to claim 13, the contraction and volume parameters detected by Burnes et al. are indicative of congestive heart failure, para 0002-0003.

In regard to claim 14, Burnes et al. apply a cardiac resynchronization therapy, para 0012.

### ***Conclusion***

10. The finality of the last Office action has been withdrawn in view of the new grounds of rejection. This action is made **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

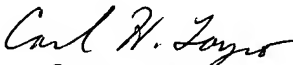
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BTG

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